

§ 431.420

(iv) If an application is approved, the final special terms and conditions, waivers, expenditure authorities, and award letter sent to the State.

(v) If an application is denied, the disapproval letter sent to the State.

(vi) The State acceptance letter, as applicable.

(vii) Specific requirements related to the approved and agreed upon terms and conditions, such as implementation reviews, evaluation design, quarterly progress reports, annual reports, and interim and/or final evaluation reports.

(viii) Notice of the demonstration's suspension or termination, if applicable.

(2) To ensure that the public has access to all documentation related to the demonstration project, including the aforementioned items, we will also provide a link to the State's public Web site.

(g) *Exemption from the normal public notice process.* (1) CMS may waive, in whole or in part, the Federal and State public notice procedures to expedite a decision on a proposed demonstration or demonstration extension request that addresses a natural disaster, public health emergency, or other sudden emergency threats to human lives.

(2) The Secretary may exempt a State from the normal public notice process or the required time constraints imposed in this section or § 431.408(a) of this subpart when the State demonstrates to CMS the existence of unforeseen circumstances resulting from a natural disaster, public health emergency, or other sudden emergency that directly threatens human lives that warrant an exception to the normal public notice process.

(i) The State is expected to discharge its basic responsibilities in submitting demonstration applications to the Secretary as required in § 431.412 of this subpart.

(ii) Such applications will be posted on the CMS Web site.

(3) A State must establish (or meet) all of the following criteria to obtain such an exemption from the normal public notice process requirements:

(i) The State acted in good faith, and in a diligent, timely, and prudent manner.

42 CFR Ch. IV (10–1–13 Edition)

(ii) The circumstances constitute an emergency and could not have been reasonably foreseen.

(iii) Delay would undermine or compromise the purpose of the demonstration and be contrary to the interests of beneficiaries.

(4) CMS will publish on its Web site any disaster exemption determinations within 15 days of approval, as well as the revised timeline for public comment or post-award processes, if applicable.

§ 431.420 Monitoring and compliance.

(a) *General.* (1) Any provision of the Social Security Act that is not expressly waived by CMS in its approval of the demonstration project are not waived, and States may not stop compliance with any of these provisions not expressly waived. Waivers may be limited in scope to the extent necessary to achieve a particular purpose or to the extent of a particular regulatory requirement implementing the statutory provision.

(2) States must comply with the terms and conditions of the agreement between the Secretary and the State to implement a State demonstration project.

(b) *Implementation reviews.* (1) The terms and conditions will provide that the State will perform periodic reviews of the implementation of the demonstration.

(2) CMS will review documented complaints that a State is failing to comply with requirements specified in the special terms and conditions and implementing waivers of any approved demonstration.

(3) CMS will promptly share with the State complaints that CMS has received and will also provide notification of any applicable monitoring and compliance issues.

(c) *Post award.* Within 6 months after the implementation date of the demonstration and annually thereafter, the State must hold a public forum—

(1) To solicit comments on the progress of a demonstration project.

(2) At which members of the public have an opportunity to provide comments and in such time as to include a summary of the forum in the quarterly report associated with the quarter in

which the forum was held, as well as in its annual report to CMS.

(3) The public forum to solicit feedback on the progress of a demonstration project must occur using one of the following:

(i) A Medical Care Advisory Committee that operates in accordance with § 431.412 of this subpart.

(ii) A commission or other similar process, where meetings are open to members of the public, and would afford an interested party the opportunity to learn about the demonstration's progress.

(iii) The State must publish the date, time, and location of the public forum in a prominent location on the State's public Web site, at least 30 days prior to the date of the planned public forum.

(4) [Reserved]

(d) *Terminations and suspensions.* (1) The Secretary may suspend or terminate a demonstration in whole or in part, any time before the date of expiration, whenever it determines that the State has materially failed to comply with the terms of the demonstration project.

(2) The Secretary may also withdraw waivers or expenditure authorities based on a finding that the demonstration project is not likely to achieve the statutory purposes.

(3) The terms and conditions for the demonstration will detail any notice and appeal rights for the State for a termination, suspension or withdrawal of waivers or expenditure authorities.

(e) *Closeout costs.* When a demonstration is terminated, suspended, or if waivers or expenditure authority are withdrawn, Federal funding is limited to normal closeout costs associated with an orderly termination of the demonstration or expenditure authority, including service costs during any approved transition period, and administrative costs of disenrolling participants.

(f) *Federal evaluators.* (1) The State must fully cooperate with CMS or an independent evaluator selected by CMS to undertake an independent evaluation of any component of the demonstration.

(2) The State must submit all requested data and information to CMS or the independent evaluator.

§ 431.424 Evaluation requirements.

(a) *General.* States are permitted and encouraged to use a range of appropriate evaluation strategies (including experimental and other quantitative and qualitative designs) in the application of evaluation techniques with the approval of CMS.

(b) *Demonstration evaluations.* Demonstration evaluations will include the following:

(1) *Quantitative research methods.* (i) These methods involve the empirical investigation of the impact of key programmatic features of the demonstration.

(ii) CMS will consider alternative evaluation designs when quantitative designs are technically infeasible or not well suited to the change made by the demonstration.

(2) *Approaches that minimize beneficiary impact.* The evaluation process must minimize burden on beneficiaries and protect their privacy in terms of implementing and operating the policy approach to be demonstrated while ensuring the impact of the demonstration is measured.

(c) *Evaluation design plan.* (1) The State will submit and receive CMS approval of a design for an evaluation of the demonstration project and publish this document to the State's public Web site within 30 days of CMS approval.

(2) The draft demonstration evaluation design must include all of the following:

(i) A discussion of the demonstration hypotheses that are being tested including monitoring and reporting on the progress towards the expected outcomes.

(ii) The data that will be utilized and the baseline value for each measure.

(iii) The methods of data collection.

(iv) A description of how the effects of the demonstration will be isolated from those other changes occurring in the State at the same time through the use of comparison or control groups to identify the impact of significant aspects of the demonstration.